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| EXAMINER | |
|---|---|
| WORLEY, CATHY KINGDON | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/544,180 | MOHNEN ET AL. | |
| | Examiner | Art Unit | |
| | CATHY K. WORLEY | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,4-11,13-16,19-24 and 26* is/are pending in the application.

4a) Of the above claim(s) *6-10,14,15 and 19-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,11,13,16 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. The amendment filed Feb.29, 2008, has been entered.

2. Claims 3, 12, 17, 18, and 25 have been canceled.

Claim 26 has been newly added and is drawn to the elected invention.

Claims 1, 2, 4-11, 13-16, 19-24, and 26 are pending.

Claims 6-10, 14, 15, and 19-24 are withdrawn.

3. Claims 1, 2, 4, 5, 11, 13, 16, and 26 are examined in the present office action.

4. This application contains claims 6-10, 14, 15, and 19-24 drawn to inventions nonelected with traverse in the response filed July 9, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### *Rejections and Objections that are withdrawn*

6. The objections to the specification for the description of Figure 3, the use of hyperlinks, and the use of the trademark SEPHAROSE are withdrawn in light of the Applicant's amendments to the specification.

7. The objections to claims 3, 5, 11, and 12 are withdrawn in light of the Applicant's amendments to the claims.

8. The rejections of claims 3-5 and 25 under 35 USC 112, second paragraph, are withdrawn in light of the Applicant's amendments to the claims.

9. The rejections of claim 5 under 35 USC 112, first paragraph, for lack of written description and enablement are withdrawn in light of the Applicant's amendments to the claims.

10. The rejection of claim 16 under 35 U.S.C. 102(b) as being anticipated by Khan A. A. is withdrawn in light of the Applicant's amendments to the claims.

***Specification***

11. The abstract remains objected to because it should specify the gene that has been elected for prosecution; in particular, it should specify that it is the Arabidopsis GalAt1 gene.

12. The title of the invention remains objected to because the amendment introduces a typographical error. The amendment inserts "(GALATI1)"; and this should be - - (GALAT1) - - . Appropriate correction is requested.

***Claim Rejections - 35 USC § 112***

13. Claims 1, 2, 4, 5, 11, 13, 16 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new rejection that was necessitated by the Applicant's amendment of claim 1. All dependent claims are included in this rejection.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for

example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 1 recites the broad recitation "galacturonosyltransferase", and the claim also recites "(GALAT1)" which is the narrower statement of the range/limitation. It is unclear of the polypeptides encoded by the recited nucleic acids must have the same substrates and characteristics as the GALAT1 enzyme, or if the polypeptides can have any galacturonosyltransferase activity.

14. Claims 1, 2, 4, 11, 13, and 16 remain rejected and new claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record stated in the previous Office Action mailed on Aug. 29, 2007, and for the reasons stated below. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant's arguments in the response filed on Feb. 29, 2008, were fully considered but were not found to be persuasive.

The claims are broadly drawn to isolated nucleic acids encoding a polypeptide having galacturonosyltransferase (GALAT1) activity, and to polypeptides having

50% similarity with SEQ ID NO:2, and to vectors and plants comprising said nucleic acids. The new claim is directed to a nucleic acid having at least 90% identity to SEQ ID NO:1 that encodes a polypeptide having GALAT1 activity.

The essential feature of the nucleic acids of the instant invention is that they encode polypeptides that have galacturonosyltransferase activity (see page 7, lines 6-7; and see the recitation in claim 1).

The Applicants describe the nucleic acid of SEQ ID NO:1 (also referred to as At3g61130) which encodes the polypeptide of SEQ ID NO:2 (see pages 28-29 and the sequence listing). The Applicants describe a bioinformatics search that identified 10 genes with 23-29% sequence identity, and they describe several motifs and conserved residues that are present in these genes (see page 18 and figure 7). The Applicants describe the polypeptide pf SEQ ID NO:2 as having galacturonosyltransferase activity (see page 9, lines 24-25 and Figure 8).

The Applicants do not describe any polypeptides having 50% identity to SEQ ID NO:2 other than SEQ ID NO:2, itself, that are known to comprise galacturonosyltransferase activity. Nor do they describe any polypeptides encoded by a nucleic acid having 90% identity to SEQ ID NO:1 (other than SEQ ID NO:2) that are known to have galacturonosyltransferase activity.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of

a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Applicants fail to describe a representative number of polypeptides that have GalAT activity or polypeptides having as little as 50% identity to SEQ ID NO:2 that have GalAT activity or polypeptides encoded by nucleic acids with 90% identity to SEQ ID NO:1 that have GalAT activity, and they fail to describe a representative number of nucleic acids encoding such polypeptides. The Applicants only describe the polypeptide of SEQ ID NO:2, and one nucleic acid encoding it, SEQ ID NO:1. Furthermore, the Applicants fail to describe structural features common to members of the claimed genus of polypeptides that have GalAT activity. They merely disclose motifs found in a bioinformatics search utilizing amino acid sequences for which there has not been any activity empirically determined. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for GalAT activity, it remains unclear what features identify polypeptides capable of such activity. Since the genus of polypeptides and nucleic acids encoding such polypeptides has not been described by specific structural features, the specification

fails to provide an adequate written description to support the breadth of the claims.

SEQ ID NO:2 consists of 673 amino acids. Polypeptides that have as little as 50% identity to SEQ ID NO:2 can have 336 amino acid substitutions within the polypeptide; therefore, this genus of molecules encompasses $20^{336}$ molecules. Nucleic acids encoding these polypeptides encompass an even larger genus of molecules because of codon redundancy. Nucleic acids with as little at 90% identity to SEQ ID NO:1 can have 202 substitutions because SEQ ID NO:1 is 2022 nucleotides in length. Therefore this genus of nucleic acids encompasses $4^{202}$ molecules. Furthermore, if each of those 202 substitutions can cause a change in the amino acid encoded by the particular codon, then the resulting polypeptide can have 202 amino acid substitutions relative to SEQ ID NO:2 which results in a protein having as little as 70% identity to SEQ ID NO:2. In addition, claim 1 does not provide any structural limitations at all, and this encompasses an infinite number of molecules.

Nucleic acids that encode polypeptides with as little as 50% identity to SEQ ID NO:2 or that have 90% identity to SEQ ID NO:1 encompass multitudes of molecules, many of which would not produce a polypeptide with GalAT activity upon being transcribed in a plant cell, and most of which were not in the possession of the Applicant at the time of filing. Furthermore, claim 1 does not comprise any structural limitations at all, and therefore it comprises an infinite number of

molecules. The Applicants have only reduced one molecule to practice in an experiment that demonstrates GalAT activity. Accordingly, the specification fails to provide an adequate written description to support the genus of nucleic acids that encode polypeptides with 50% identity to SEQ ID NO:2 that comprise GalAT activity or that have 90% identity to SEQ ID NO:1 and encode polypeptides that comprise GalAT activity as set forth in the claims. (See Written Description guidelines published in the Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices: p. 1099-1111).

The Applicant argues that the specification provides a list of sequences that encode active GalAT polypeptides (see third paragraph on page 19 of the response). This is not persuasive, however, because the list of genes in the specification that is referred to is a list of members of a "proposed" GALAT gene family. There is nothing to indicate that these nucleic acids have been shown to encode proteins that have GalAT activity.

The Applicant argues that the specification teaches at page 22 that some variation in sequence can be tolerated so that enzymatic activity could be maintained (see third paragraph on page 19 of the response). This is not persuasive, however, because page 22 of the specification merely provides protocols for assaying GalAT activity, it does not provide any guidance about what domains or motifs of SEQ ID NO:2 are sufficient for comprising GalAT activity.

The Applicant argues that they have provided guidance concerning parts of the protein which should be conserved by way of disclosing amino acids that are conserved amongst the GALAT family (see third paragraph on page 19 of the response). This is not persuasive, however, because the conserved amino acids have not been shown to be sufficient for comprising GALAT activity, it is merely a bioinformatics approach to analyzing the amino acid sequences of putative or proposed GALAT enzymes.

The Applicant asserts that they have stated that polypeptides with at least 50% sequence identity to SEQ ID NO:2 have GALAT activity, and the Patent Office should accept the inventor's assertions in their field of scientific expertise (see third paragraph on page 19 of the response). This is not persuasive, however, because the applicants have not provided any evidence that proteins with as little as 50% identity to SEQ ID NO:2 have GALAT activity, and furthermore, in order to support a genus as large as this, the Applicants would have to have more members of this genus reduced to practice, or more information regarding motifs, domains, and structures that are known to be sufficient for comprising GALAT activity.

15. Claims 1, 2, 4, 11, 13, and 16 remain rejected and new claim 26 is rejected under 35 U.S.C. 112, first paragraph, for the reasons of record stated in the previous Office Action mailed on Aug. 29, 2007, and for the reasons stated below, because the specification, while being enabling for nucleic acids encoding the full-

length polypeptide of SEQ ID NO:2, and vectors and plants comprising such nucleic acids, does not reasonably provide enablement for nucleic acids encoding polypeptides with approximately 50% similarity to SEQ ID NO:2, or nucleic acids having at least 90% identity to SEQ ID NO:1; or nucleic acids encoding polypeptides with no structural limitations at all. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The Applicant's arguments in the response filed on Feb. 29, 2008, were fully considered but were not found to be persuasive.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to isolated nucleic acids encoding a polypeptide having galacturonosyltransferase (GalAT) activity, and to polypeptides having 50%

similarity with SEQ ID NO:2, and to vectors and plants comprising said nucleic acids, and to nucleic acids having at least 90% identity to SEQ ID NO:1.

The Applicants teach the nucleic acid of SEQ ID NO:1 (also referred to as At3g61130) which encodes the polypeptide of SEQ ID NO:2 (see pages 28-29 and the sequence listing). The Applicants disclose a bioinformatics search that identified 10 genes with 23-29% sequence identity, and they teach several motifs and conserved residues that are present in these genes (see page 18 and figure 7). However, none of the other genes identified have been shown to encode proteins that have GalAT activity. The Applicants teach that the polypeptide of SEQ ID NO:2 (At3g61130) has GalAT activity (see page 9, lines 24-25 and Figure 8).

The Applicants do not teach any polypeptides having 50% identity to SEQ ID NO:2 (other than SEQ ID NO:2, itself) that are known to have GalAT activity. The Applicants do not teach any nucleic acids having as little as 90% identity to SEQ ID NO:1 that encode polypeptides with GalAT activity (other than SEQ ID NO:1, itself).

The instant specification fails to provide guidance for which amino acids of SEQ ID NO:2 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain GalAT activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

Making substitutions in proteins does not produce predictable results. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1).

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding multitudes polypeptides with 50% identity to SEQ ID NO:2, or polypeptides with no structural relationship to SEQ ID NO:2 or polypeptides encoded by nucleic acids having as little as 90% identity to SEQ ID NO:1. Making all possible single amino acid substitutions in a 673 amino acid long protein such as SEQ ID NO:2 would require making and analyzing $19^{673}$ nucleic acids; these proteins would have 99.9% identity to SEQ ID NO:2. Because nucleic acids encoding proteins with 50% identity to SEQ ID NO:2 would encode proteins with 336 amino acid substitutions, many more than $19^{673}$ nucleic acids

would need to be made and analyzed. Given that claim 1 has not structural limitations, there is an infinite number of nucleic acids and polypeptides that would have to be made and analyzed for GalAT activity.

The state of the prior art is such that one of skill in the art cannot predict how many amino acid substitutions can be tolerated and which residues can be substituted without losing enzymatic activity. For example, Guo et al (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph 2). Thus, making and analyzing proteins with 336 amino acid substitutions relative to SEQ ID NO:2 or that have no structural relationship to SEQ ID NO:2 that also have GalAT activity would require undue experimentation.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of skill in the art to make and use the multitudes of polypeptides encompassed by the claims.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to make and use the claimed invention, and therefore, the invention is not enabled throughout the broad scope of the claims.

The Applicant argues that the specification provides a list of sequences that encode active GalAT polypeptides (see third paragraph on page 19 of the response). This is not persuasive, however, because the list of genes in the specification that is referred to is a list of members of a "proposed" GALAT gene family. There is nothing to indicate that these nucleic acids have been shown to encode proteins that have GalAT activity.

The Applicant argues that the specification teaches at page 22 that some variation in sequence can be tolerated so that enzymatic activity could be maintained (see third paragraph on page 19 of the response). This is not persuasive, however, because page 22 of the specification merely provides protocols for assaying GalAT activity, it does not provide any guidance about what domains or motifs of SEQ ID NO:2 are sufficient for comprising GalAT activity.

The Applicant argues that they have provided guidance concerning parts of the protein which should be conserved by way of disclosing amino acids that are conserved amongst the GALAT family (see third paragraph on page 19 of the response). This is not persuasive, however, because the conserved amino acids have not been shown to be sufficient for comprising GALAT activity, it is merely a bioinformatics approach to analyzing the amino acid sequences of putative or proposed GALAT enzymes.

The Applicant asserts that they have stated that polypeptides with at least 50% sequence identity to SEQ ID NO:2 have GALAT activity, and the Patent Office

should accept the inventor's assertions in their field of scientific expertise (see third paragraph on page 19 of the response). This is not persuasive, however, because they applicant's have not provided any evidence that proteins with as little as 50% identity to SEQ ID NO:2 have GALAT activity, and furthermore, in order to support a genus as large as this, the Applicants would have to have more working examples with different members of this genus, or more guidance regarding motifs, domains, and structures that are known to be sufficient for comprising GALAT activity.

The Applicant argues that one of ordinary skill in this art is highly educated, and that the present specification, taken with what is well known to the art, enables the practice of the invention as claimed without the burden of undue experimentation (see paragraph bridging pages 19-20 of the response). This is not persuasive, however, because, as discussed above, there is a high degree of unpredictability in making substitutions in proteins and there is not enough guidance in the specification about what amino acids can be deleted, substituted, or inserted and still retain GalAT activity.

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in

section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1, 2, 11, 13, and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Harper et al (US 2002/0160378, published on Oct. 31, 2002).

The claims are drawn to isolated nucleic acids encoding a polypeptide having galacturonosyltransferase (GalAT) activity, and to polypeptides having 50% similarity with SEQ ID NO:2, and to vectors and plants comprising said nucleic acids.

Harper et al teach a nucleic acid encoding a protein with 53.7% identity to the instant SEQ ID NO:2, and they refer to this nucleic acid as SEQ ID NO:1120 (see sequence alignment). They teach a method of producing a transgenic plant with altered responsiveness to at least one stress condition by introducing the nucleic acid of SEQ ID NO:1120 into the plant (see claim 29) including wherein the nucleic acid is operably linked to a heterologous promoter (see claim 35). They teach transgenic plants and seeds (which are progeny) produced by this method (see claims 42 and 44). Although they are silent with regard to any galacturonosyltransferase activity, the protein encoded by this nucleic acid has 53.7% identity to the instant SEQ ID NO:2, and this is within the claimed identity (see claim 2). Therefore, if 53.7% identity is sufficient for conferring galacturonosyltransferase activity to a protein, then the protein expressed by the method taught by Harper et al would inherently comprise such activity.

The USPTO does not have a laboratory to test for galacturonosyltransferase activity, and therefore, the burden shifts to the Applicant to demonstrate that that the prior art nucleic acid does not anticipate the claimed nucleic acids. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

17. Claims 1, 2, 11, 13, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al (US 2004/0034888, published on Feb. 19, 2004, and filed on April 28, 2003, with priority to May 6, 1999).

The claims are drawn to isolated nucleic acids encoding a polypeptide having galacturonosyltransferase (GalAT) activity, and to polypeptides having 50% similarity with SEQ ID NO:2, and to vectors and plants comprising said nucleic acids.

Liu et al teach a nucleic acid encoding a protein with 64.1% identity to the instant SEQ ID NO:2, and they refer to this nucleic acid as SEQ ID NO: 32781 (see sequence alignment). They teach a method of producing a transgenic plant having an improved property by introducing a construct comprising a promoter operably joined to the nucleic acid of SEQ ID NO: 32781 into the plant (see claim 3). They teach transgenic plants and offspring produced by this method (see page 8, paragraph 0081). Although they are silent with regard to any

galacturonosyltransferase activity, the protein encoded by this nucleic acid has 64.1% identity to the instant SEQ ID NO:2, and this is within the claimed identity (see claim 2). Therefore, if 64.1% identity is sufficient for conferring galacturonosyltransferase activity to a protein, then the protein expressed by the method taught by Harper et al would inherently comprise such activity.

The USPTO does not have a laboratory to test for galacturonosyltransferase activity, and therefore, the burden shifts to the Applicant to demonstrate that that the prior art nucleic acid does not anticipate the claimed nucleic acids. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 1, 2, 11, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brummell et al (PMB (2001) Vol. 47, pp. 311-340) in view of Tavares et al (PMB (2000) Vol. 42, pp. 703-717).

The claims are drawn to isolated nucleic acids encoding a polypeptide having galacturonosyltransferase (GalAT) activity, and to polypeptides having 50% similarity with SEQ ID NO:2, and to vectors and plants comprising said nucleic acids.

The instant claims are obvious over the prior art because there had been a recognized need in the art to develop methods to manipulate fruit ripening and plant cell walls, there had been a finite number of identified predictable potential solutions, including manipulating glycosyltransferases in transgenic plants, and one of ordinary skill in the art could have pursued any of the potential options with a reasonable expectation of success at the time of the invention.

Brummell et al teach that cell wall metabolism is important for fruit softening and quality, and this metabolism is carried out by numerous enzymes associated with different modifications to carbohydrates in the cell wall (see entire article). They teach that suppression and over-expression of the enzymes in transgenic plants is preferred over *in vitro* methods for the study of function of the enzymes (see second paragraph in left column on page 312).

They do not teach a nucleic acid encoding a polypeptide with at least 50% identity to SEQ ID NO:2.

Tavares et al teach a nucleic acid encoding a polypeptide with 90.5% identity to SEQ ID NO:2 (see alignment), they refer to this polypeptide as LGT1 and they identify it as a glycosyltransferase (see paragraph bridging left and right columns on page 704). They teach that it catalyses the transfer of glycosyl groups to a carbohydrate core (see right column on page 704).

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to modify the transgenic plants taught by Brummell et al to utilize any of the glycosyltransferases that were commonly known in the art; especially one, such as the LGT1 taught by Tavares that is taught to catalyze the transfer of glycosyl groups to a carbohydrate core. The use of strong constitutive promoters to drive high levels of expression was known in the art at the time of filing, and it would have been obvious to utilize a strong promoter to drive expression of the LGT1 nucleic acid in a transgenic plant. It would have been obvious to produce offspring of such plants. One of ordinary skill would have had an expectation of success in producing such plants, and one would have expected the result would be a change in the carbohydrates and structures in the cell walls of the plants.

Although Tavares et al are silent with regard to any galacturonosyltransferase activity, the protein encoded by this nucleic acid has 90.1% identity to the instant SEQ ID NO:2, and this is within the claimed identity (see claim 2). Therefore, if 90.1% identity is sufficient for conferring

galacturonosyltransferase activity to a protein, then the protein expressed by the method taught by Tavares et al would comprise such activity, and this would naturally flow from the combination of the teachings.

The USPTO does not have a laboratory to test for galacturonosyltransferase activity, and therefore, the burden shifts to the Applicant to demonstrate that that the prior art nucleic acid does not render obvious the claimed nucleic acids. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/
Patent Examiner, Art Unit 1638